



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0247]

Food and Drug Administration Transparency Initiative: Exploratory Program to Increase Access to the Agency's Compliance and Enforcement Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Food and Drug Administration Transparency Initiative: Exploratory Program to Increase Access to the Agency's Compliance and Enforcement Data," as part of the Transparency Initiative. This report includes eight initiatives adopted by the Commissioner of Food and Drugs (the Commissioner) to explore avenues for making FDA's publicly available compliance and enforcement data more accessible and user-friendly.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

FDA is announcing the availability of a report entitled “Food and Drug Administration Transparency Initiative: Exploratory Program to Increase Access to the Agency’s Compliance and Enforcement Data.” FDA is responsible for a broad range of compliance and enforcement activities. Increasing the transparency of these activities enhances the public’s understanding of the Agency’s decisions and promotes accountability of the Agency and the regulated industry.

In a May 6, 2011, memorandum to the Department of Health and Human Services responding to a January 18, 2011, Presidential Memorandum on Regulatory Compliance, (76 FR 3825, January 21, 2011), FDA recounted the actions it had already implemented, as well as those proposed or underway, to increase public accessibility of its regulatory compliance and enforcement information. FDA stated that it would: (1) Issue proposals for public comment within 150 days (by October 3, 2011) if it concluded that there were additional opportunities to increase the transparency of its compliance and enforcement data, and (2) determine within 270 days (by January 31, 2012) whether to adopt such proposals.

On October 3, 2011, FDA issued a report entitled “Food and Drug Administration Transparency Initiative: Draft Proposals for Public Comment to Increase Transparency by Promoting Greater Access to the Agency’s Compliance and Enforcement Data,” that advanced eight draft proposals to make FDA’s publicly available compliance and enforcement data more accessible and user-friendly

(<http://www.fda.gov/downloads/AboutFDA/Transparency/TransparencyInitiative/UCM273145.pdf>). In publishing a notice of availability of this report on October 4, 2011 (76 FR 61366), FDA sought public comment on these proposals by December 2, 2011. The Agency stated that its Transparency Task Force would ultimately recommend specific draft proposals to the Commissioner for consideration based on the comments it received, the feasibility of each draft proposal, relative priority, and available resources, and that the Commissioner would determine whether to adopt any of these draft proposals by January 31, 2012.

Based on a review of the recommendations of the Transparency Task Force, the Commissioner is adopting all eight of the draft proposals published in October 2011 as initiatives the Agency will explore, thereby committing the Agency to investigating numerous avenues for increasing the transparency and public accessibility of its compliance and enforcement data.

Dated: January 27, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

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